Evidence-Based Financial Incentives for Healthcare Reform

Putting It Together

George A. Diamond, MD; Sanjay Kaul, MD

“Bit by bit, putting it together
Piece by piece, only way to make a work of art
Every moment makes a contribution
Every little detail plays a part.
Having just a vision’s no solution,
Everything depends on execution
Putting it together, that’s what counts!”

—Stephen Sondheim

Once, on hearing a colleague claim that the details of his new theory remained to be sketched in, Nobel laureate Wolfgang Pauli drew a crude rectangle on the chalkboard, and said, “Here is the proof that I am as great an artist as Rembrandt; only the details remain to be sketched in.”

Current proposals for healthcare reform have been similarly described as rough “…sketches rather than finished portraits, with many important details yet to be revealed.”

Each, for example, promises to link payment incentives to outcomes and performance; but none provide any specifics regarding the substance of these incentives. In this essay, we describe a specific strategy for structuring these incentives around the existing empirical evidence of clinical benefit, and outline its potential for improving the quality and reducing the cost of health care. We term this approach evidence-based reimbursement.

Evidence-Based Reimbursement Versus Pay for Performance

Some might see a surface similarity between the idea of evidence-based reimbursement and so-called “pay-for-performance” strategies, which have been widely adopted (in various forms) as models for provider-payment healthcare reform. They are not the same. In general, pay-for-performance strategies seek to reward physicians for meeting certain predefined benchmarks of quality health care. These benchmarks are usually defined in terms of established guidelines or ad hoc criteria for the detection and appropriate management of common clinical conditions such as hypertension and hyperlipidemia. In its simplest implementation, physicians who adhere to these benchmarks are rewarded at annual intervals with a monetary bonus. The American College of Cardiology has defined the following 12 desiderata for the optimal design of such programs:

1. Use evidence-based performance measures.
2. Design a sustainable business model to encourage high-quality care.
3. Reward process, outcome, improvement, and sustained high performance.
4. Assign credit in ways that are credible and encourage collaboration.
5. Use clinical data over administrative claims data.
6. Set national performance targets.
7. Use appropriateness criteria derived from empirical evidence and consensus opinion.
9. Permit auditing of performance by third parties and by the participants themselves.
10. Establish transparent provider ratings.
11. Avoid perverse incentives with unintended consequences.
12. Invest in outcomes and health-services research.

Although most pay-for-performance programs fall short of these rather lofty aims, they are nevertheless expanding exponentially around the country. Med-Vantage lists 148 such programs through December 2007. This rapid growth is occurring despite a paucity of empirical evidence that pay-for-performance programs actually deliver on their promise to improve the quality and reduce the cost of health care. There are essentially no randomized controlled trials demonstrating the effectiveness of pay-for-performance programs and very few reports in the literature that analyze the existing programs.

Furthermore, there are serious reasons to doubt that the pay-per-performance strategy could stand up to such scrutiny. Consider, for example, its emphasis on aggregate patterns of behavior rather than case-by-case decisions and practices (desideratum No. 8). This key design feature flies in the face of everything we know about the actual practice of medicine. As any practicing physician will attest, the expected benefit associated with a particular therapy varies widely from
Evidence-based ‘‘fee-for-benefit’’ reimbursement strategy, by which the monetary payment for provision of care is independent of its expected clinical benefit, is illustrated by the horizontal line in the Figure. According to this strategy, payment for revascularization of a symptomatic stenosis is higher than for an asymptomatic stenosis. This evidence-based reimbursement strategy thereby provides a financial incentive to the physician for the preferential treatment of symptomatic disease as a consequence of its greater expected therapeutic benefit. Simply put, if reimbursement can drive utilization and utilization can drive outcome, reimbursement can drive outcome.

Evidence-based reimbursement incentives focus on expected benefit rather than actual benefit, recognizing that even a bad decision can result in a good outcome, and a good decision can result in a bad outcome. Accordingly, physicians are not held accountable for the actual outcomes, but only for the quality of their decisions leading to those outcomes.

Outcomes databases are nevertheless an important complement to our strategy. Presently, outcomes databases offer us broad assessments of the quality of care, but they cannot by themselves improve the quality or control the cost of that care because they do not provide any direct incentives for doing so. Evidence-based reimbursement does. In this context, the role of the outcomes database is to document the extent to which the expected benefits are actually achieved (on average) and to serve as the foundation for developing validated prediction models to assist the physician in predicting therapeutic benefit for individual patients.

As with pay-for-performance, individual providers might be further rewarded (or penalized) if the observed improvement in outcome under their care is better (or worse) than that predicted by the model (presumably because the quality of care rendered by these providers differs from that of the putative standard provider). These additional adjustments provide an incentive to optimize actual benefit as well as expected benefit. Hence, the empirical data contained in the outcomes database provides the means to ensure that the most effective medical decision-making consistently receives the greatest reward.

These incentives can be a powerful mechanism for improving utilization, whereas simultaneously controlling costs and mitigating the widespread inequities resulting from cost shifting, practice variation and arbitrary ad hoc consensus judgments of appropriateness. Instead, therapeutic benefit is explicitly defined in terms of the most natural of clinical outcomes—improved survival and quality of life based on existing clinical trial evidence. And because quality-of-life assessments are inherently subjective, who better make such value judgments than the patients themselves?

Key differences between pay-for-performance and evidence-based reimbursement are summarized in Table 1. Unlike current pay-for-performance proposals, for which there is little direct evidence of effectiveness, these evidence-based reimbursement incentives (1) focus on the expectation of benefit rather than actual outcome, (2) use empirical data rather than expert consensus opinion, (3) apply to individual point-of-service encounters rather than remote group averages, and (4) are relatively large in size and immediate in impact. The importance of this final point should be self-evident to any parent. Just try to modify behavior with the hollow promise of relatively small rewards delayed long into the future.
Let us now apply this evidence-based reimbursement strategy to the management of chronic stable angina to show precisely how it can increase the quality and reduce the cost of care.

Evidence-Based Reimbursement for the Management of Chronic Stable Angina

Despite a preponderance of evidence supporting plaque instability as the proximate cause of atherosclerotic events,21,22 treatment strategies continue to focus on the anatomic stenosis.23,24 This preoccupation with coronary luminoLOGY is what causes clinicians to perform stress tests and angiograms to identify flow-limiting lesions, even among asymptomatic patients, and to mitigate the effects of these lesions by direct mechanical intervention. As a result, ≈500,000 patients per year undergo percutaneous coronary intervention (PCI) for treatment of chronic stable angina at an approximate cost (hospital and physician fees) of $20,000 per case—an expenditure of $10 billion annually.25

Unlike coronary bypass surgery, however, there is no evidence that PCI (with or without the use of intravascular stents) prolongs the survival of patients with chronic stable angina,26 or that it improves the quality of life of patients with asymptomatic disease or silent ischemia.27 Therefore, on the basis of the evidence, PCI is considered formally appropriate only if the patient has (1) ischemic symptoms that might be improved by revascularization, (2) objective evidence of ischemia by stress testing, and (3) failed a trial of optimal medical management because the ischemia is intractable to maximally tolerated doses of antiischemic medications.

Nevertheless, empirical studies document that ≈10% to 20% of patients referred for PCI are asymptomatic,28 as many as 30% of symptomatic patients are taking no antiischemic medications,29 at least 50% of patients have not had a stress test,16 and an unknown number of the stress tests that are performed are negative. Consequently, a large number of the 500,000 PCI’s performed each year are insufficiently justified and may be inappropriate.

Even the conventionally positive stress test can be questioned as a justification for PCI. Many stress laboratories routinely discontinue antiischemic drugs 48 to 72 hours before testing—ostensibly to minimize the occurrence of false-negative responses. This is entirely reasonable when testing is conducted for purposes of diagnosis, but it is unreasonable if the purpose is to determine the effectiveness of medical therapy. As a result, a patient who is well controlled on medical therapy can be misjudged to be at high risk for an ischemic event and in need of PCI.

In his sociological dissection of the medical profession,30 the late Eliot Freidson identified 5 characteristics of the typical clinician that help to explain these patterns of misutilization: (1) Clinicians believe in what they are doing; (2) they prefer action, even with little chance of success, over no action at all; (3) they see apparent cause/effect relationships even in their absence; (4) they depend more on personal judgment than on empirical evidence; and (5) when things go wrong, they chalk it up to chance.

These characteristics were on vivid display in a recent study in which practicing cardiologists were presented hypothetical scenarios of patients with stable coronary disease and prompted to talk through their decision-making process. They uniformly favored PCI by such a large and consistent margin that it would be fair to characterize them as having been seized by an “oculostenotic reflex” in which any sign of angiographic narrowing trumped any evidence regarding ischemic dysfunction.31

Consider the results of the recent COURAGE (Clinical Outcomes Utilizing Revascularization and Aggressive druG Evaluation) trial, for instance.26,27,32 This was a clinical trial of more than 2000 patients with mild to moderate chronic stable angina randomized to an initial management strategy of optimal medical therapy alone or optimal medical therapy plus PCI. Over a follow-up of 4.6 years, there was no significant difference in the primary outcome of all-cause mortality or myocardial infarction.26 Although optimal medical therapy plus PCI was associated with significantly greater improvement in anginal frequency and quality-of-life, the magnitude of marginal benefit was small and persisted for no more than 2 years.27 More recently, an economic analysis of COURAGE reported that the cost per year of quality adjusted survival exceeded conventional thresholds of cost-effectiveness.32

The COURAGE investigators thereby concluded that optimal medical therapy is the preferred initial management strategy for patients with stable coronary disease.

Despite the transient nature of the benefit and the added economic burden demonstrated in COURAGE, Kirtane and Cohen35 nonetheless maintain that PCI is “…clearly beneficial…”, saying “…the fact that PCI led to significantly greater and more rapid improvement in angina and quality of life with no excess of complications mandates that physicians should continue to provide PCI to patients who, when informed of the true risks and benefits of the procedure, request that it be performed for symptomatic relief.”

If this hyperbolic rhetoric rings true, try replacing “PCI” with a more contentious alternative such as “late-term abortion” or “euthanasia.” In this protean ethical environment, evidence-based reimbursement can help stabilize the balance between our societal and professional responsibilities.

To illustrate precisely how an evidence-based reimbursement strategy might be applied to the treatment of patients with stable coronary disease, we begin by summarizing the

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**Table 1. Comparison of Alternative Incentive Systems for Healthcare Reform**

<table>
<thead>
<tr>
<th>Incentive</th>
<th>Pay for Performance</th>
<th>Evidence-Based Reimbursement</th>
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<tbody>
<tr>
<td>Target Basis</td>
<td>Aggregate patient outcomes</td>
<td>Individual physician decisions</td>
</tr>
<tr>
<td>Magnitude</td>
<td>Small</td>
<td>Large</td>
</tr>
<tr>
<td>Timing</td>
<td>Delayed</td>
<td>Immediate</td>
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<tr>
<td>Impact</td>
<td>Minor</td>
<td>Major</td>
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"...the fact that PCI led to significantly greater and more rapid improvement in angina and quality of life with no excess of complications mandates that physicians should continue to provide PCI to patients who, when informed of the true risks and benefits of the procedure, request that it be performed for symptomatic relief.”
This fall in revenue provides a compelling incentive to encourage greater adherence with the prerequisite criteria, because such adherence will be rewarded promptly by higher levels of reimbursement. For example, although reimbursement is only $8000 for the 255,000 patients with symptoms when ischemia is not documented by a positive stress test nor shown to be refractory to medical therapy, it goes up to $24,000 when such criteria have been met before PCI. Of course, if the stress test is negative or if optimal medical therapy ameliorates the ischemia, reimbursement will be proportionally less because the expectation of benefit is less. Consequently, practitioners might turn to new revenue streams to replace these losses. One such avenue involves more aggressive preventive management of atherosclerosis.

In this way, evidence-based reimbursement does not encourage the denial of care; it encourages more appropriate care given the available evidence. Because the strategy is directed not only at the individual physician, but at the hospitals and outpatient facilities where the care is provided, the shared financial incentives thereby promote partnerships between physicians and administrators to establish and maintain accountability for appropriate utilization. And by phasing the program in—say, over 5 years—these providers would have the time to redirect their activities to these more efficient, effective and profitable avenues of care.

### Additional Applications of Evidence-Based Reimbursement

#### Principal Targets

We do not propose that evidence-based reimbursement is applicable to all of health care. Most medical care is not based on formal empirical evidence of benefit and most clinical guidelines rely more on consensus opinion than on clinical trial observations. Nevertheless, just as Pareto showed that ≈80% of a country’s wealth is held by 20% of the populace, a similar proportion of national healthcare cost is attributable to a handful of procedures and treatments. Table 3 lists *Consumer Reports’ “Top Ten” over-used tests and procedures. These are the optimal targets for evidence-based reimbursement.*

#### Off-Label Uses

Evidence-based reimbursement could help mitigate controversies such as that regarding late thrombosis associated with drug-eluting stents. Currently, the Center for Medicare and Medicaid Services (CMS) pays for medical procedures deemed by it to be “reasonable and necessary.” This determination is fundamentally different from that by the Food and Drug Administration (FDA), through which drugs and devices are approved in terms of “safety and efficacy.” As a result, a number of drugs and devices are (paradoxically) reimbursed by CMS without having proven “safety and efficacy”—the frequent off-label use of drug-eluting stents and clopidogrel being the most immediate examples.

It is generally acknowledged (even by FDA) that physicians can legitimately use approved drugs and devices in off-label ways. But there is no similar guarantee that payers need to reimburse such off-label use at the same level of on-label use. Accordingly, CMS is free to set reimbursement

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Stress Test</th>
<th>Treatment Score</th>
<th>Payment, $</th>
<th>Patients,</th>
<th>Revenue, $</th>
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<tbody>
<tr>
<td>+</td>
<td>+</td>
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<td>1</td>
<td>24,000</td>
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<td>+</td>
<td>2/3</td>
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<td>8000</td>
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<td>-</td>
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<td>1/3</td>
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“appropriateness” of PCI for each of the 8 distinct clinical triads based on the presence or absence of our clinical prerequisites: symptoms consistent with myocardial ischemia, a stress test consistent with exercise-induced ischemia, and failure of antiischemic drug treatment. The resultant appropriateness score represents the quantitative degree to which each of the 8 clinical triads is adjudged suitable for PCI (based on the available clinical trial evidence). For simplicity, we assume that each of the prerequisites is of equal importance to this determination of appropriateness.

If we interpret these scores as proxies for “expected therapeutic benefit,” we can use them as the basis for a proportionate evidence-based reimbursement strategy. We therefore set the payment at $24,000 for a score of 1 (a 20% reward over the assumed conventional payment of $20,000 in return for adhering precisely to the appropriateness criteria), $16,000 for a score of 2 of 3 (a 20% discount for moderate nonadherence), $8,000 for a score of 1 of 3 (a 60% discount for substantial nonadherence), and $0 for a score of 0 (a 100% discount for total nonadherence). Payment is therefore linearly proportional to one’s case-by-case adherence with the evidence-based appropriateness of the procedure. Of note, the resultant payment schedule serves to discount nonadherence more than it rewards adherence. This is typical of social contracts: the incentives for obeying the rules are small; the disincentives for breaking them are large.

Table 2 summarizes the monetary payment for each of the 8 clinical triads along with the hypothetical number of patients falling into each of the 8 groups assuming 50% of patients falling into each of the 8 clinical triads based on the presence or absence of our clinical guidelines reliant more on consensus opinion than evidence-based reimbursement.
Table 3. *Consumer Reports’ Top 10 Overused Tests and Procedures*

<table>
<thead>
<tr>
<th>#</th>
<th>Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Back surgery: Do not rush to surgery for a simple slipped disk. In 90% of cases, the pain goes away on its own within 6 weeks. In stubborn cases, surgery, which can cost $20 000 plus physician’s fees, can relieve pain somewhat faster than physical therapy and medication, a recent study showed. But it also found that both groups of patients wound up with similar improvements after 2 years.</td>
</tr>
<tr>
<td>2</td>
<td>Heartburn surgery: Doctors surgically tighten a sphincter muscle that blocks stomach acid from backing up into the esophagus. But research shows the operation, which costs $1 400 or more, provides no better long-term relief than taking a proton-pump-inhibitor drug such as omeprazole (Prilosec OTC), which costs less than $1 a day.</td>
</tr>
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<td>3</td>
<td>Prostate treatments: Prostate cancer is often overtreated by surgery that costs $17 000, or by radiation therapy for $20 700 or more, plus physician’s fees, without adequate discussion of the alternatives or the high risk of distressing side effects such as incontinence or impotence. Because prostate cancer can grow slowly, sometimes the best approach is “watchful waiting.”</td>
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<tr>
<td>4</td>
<td>Implanted defibrillators. These devices, which automatically shock the heart back to normal rhythm cost some $90 000 over a lifetime. Yet one third of people who get them might not really need them, according to research reported in 2007. This year Medicare will pay for an estimated 50 000 of the devices.</td>
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<tr>
<td>5</td>
<td>Coronary stents: Billions are spent each year inserting tiny mesh tubes to prop open coronary arteries. The procedure plus heart drugs turns out not to work any better to prevent future heart attacks than heart drugs alone for patients with stable coronary artery disease, researchers reported in 2007.</td>
</tr>
<tr>
<td>6</td>
<td>Cesarean sections. They cost almost $7000, about 55% more than a standard colonoscopy, the virtual test is not cost-effective because any cancer without inserting a tube into the colon. But a study of virtual colonoscopy reported in 2007 concluded that standard colonoscopy is better at spotting smaller suspicious polyps. Though less costly than a standard colonoscopy, the virtual test is not cost-effective because any suspicious finding requires restesting with the real thing.</td>
</tr>
<tr>
<td>7</td>
<td>Whole-body screens. These CT scans, which can cost $1000 or more, are promoted for spotting early signs of cancer, heart disease, and other abnormalities. There are no proven benefits for healthy people, the US Food and Drug Administration has concluded. Plus CT scans expose patients to far more radiation than x-rays. A few CT scans a year can increase your lifetime risk of cancer.</td>
</tr>
<tr>
<td>8</td>
<td>High-tech angiography. Using a CT scan to noninvasively check coronary arteries for narrowing costs an average of $450, according to data from HealthMarkets, which sells health and life insurance through subsidiaries in 44 states. But standard angiography is sometimes still needed to confirm blockages that might require aggressive treatment.</td>
</tr>
<tr>
<td>9</td>
<td>High-tech mammography: Using software to flag suspicious breast x-rays would add $350 million a year to national costs if used for all mammograms. A 2007 study found that this technique failed to improve the cancer-detection rate significantly; yet resulted in more needless biopsies.</td>
</tr>
<tr>
<td>10</td>
<td>Virtual colonoscopy. These CT scans are being used to detect signs of cancer without inserting a tube into the colon. But a study of virtual colonoscopy reported in 2007 concluded that standard colonoscopy is better at spotting smaller suspicious polyps. Though less costly than a standard colonoscopy, the virtual test is not cost-effective because any suspicious finding requires restesting with the real thing.</td>
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for on-label use at a higher level than that for off-label use—in proportion to the available evidence of benefit.

Evidence-based reimbursement would thus provide an incentive to physicians and industry alike to conduct the additional clinical trials documenting the benefit of off-label use. Given this new evidence, manufacturers could then petition FDA for a new on-label indication—at which time CMS could rescale reimbursement accordingly.

**Prescription Drug Coverage**

Coverage for drug therapy could be similarly tied to clinical trial evidence. If CMS were to discount the price of a handful of well-proven drugs in direct proportion to their therapeutic benefit, a drug with more value would be awarded a higher discount than one with less value. For example, if drug A costs $1 per pill and is assigned a discount of 90% because it’s proven to prolong life, and drug B also costs $1 per pill but is only assigned a discount of 10% because it lacks such proof, the patient pays only 10 cents for drug A versus 90 cents for drug B. In each case, CMS covers the difference.

Because the total price has not changed, a company receiving a high discount will not see its profits erode. Instead, profits are more likely to soar as a consequence of facilitated access and favorable shifts in market share. Were federal law to allow it, CMS could even exploit the opportunity afforded by this windfall to negotiate additional volume discounts with the company, thereby offsetting some of the cost of the plan.

As a result of this evidence-based discounting strategy, better drugs become more affordable, thereby giving physicians powerful ethical and economic incentives to prescribe them. Similarly, the pharmaceutical industry is given greater incentives to verify the benefit of its drugs because it will be rewarded with compelling competitive advantages. In no case is there any attempt to micromanage the activities of individual patients and physicians (as with the current Medicare prescription drug plan). It is enough instead to sweeten the incentives, and let a properly regulated free market do the rest.

What is more, the requisite infrastructure is already in place. FDA regularly calls on expert advisory panels to help decide if new drugs meet standards of efficacy and safety. These panels could be given the additional authority to set the discount for these drugs based on the scientific evidence they are already reviewing.

**Concluding Comments**

Why should healthcare providers agree to cooperate on such radical proposals? One reason is that it is forced on them (just as Medicare forced Diagnosis Related Groups (DRGs) on hospitals in the 1980s). But we would not need to rely on force if we could convince the various parties that evidence-based reimbursement was in their collective self-interest. Axelrod’s views on the evolution of cooperation provide a compelling argument. He identifies 4 characteristics that a strategy must have if it is to engender cooperation among competing stakeholders such as payers and physicians. Evidence-based reimbursement possesses each of these desirable characteristics. First, the strategy is fair; it is based on evidence-based economic incentives that have immediate intuitive appeal because they make the individual patient’s benefit the central focus. Second, the strategy is provokable;
it swiftly penalizes each instance of poor care (that with relatively low expected benefit) by an immediate reduction in payment. Third, the strategy is forgiving; it just as swiftly rewards each instance of good care (that with relatively high expected benefit) by an immediate increase in payment, no matter how many times it has imposed a penalty for poor care in the past. Fourth, the strategy is explicit; its rules for reward and penalty are precisely defined.

The renowned evolutionary biologist, J.M. Smith, emphasizes the importance of Axelrod’s views to social contracts such as those among patients, physicians, and payers thusly:

“Suppose [we] agree not to steal, and to punish any member of the group who does steal. That, by itself, is not sufficient to guarantee stability, because the act of punishing is presumably costly, and therefore individuals would be tempted to accept the benefits of the contract but not the costs of enforcing it. Stability requires that refusal by an individual to participate in enforcing the contract should also be regarded as a breach which will be punished. At a later stage, enforcement is entrusted to a subgroup, who are rewarded for carrying it out.”

Shall we take charge of this enforcement ourselves, or shall we entrust others do it for us? Cortese and Miller39 argue for an independent controlling authority modeled after the Federal Reserve, and an independent investigational agency to define the effectiveness of drugs, devices, tests, and treatments to perform some of these functions. Although these suggestions have merit, we believe evidence-based reimbursement is the best place to begin.

Any recommended change in existing fiscal policy is likely to be met with fierce resistance—witness the periodic Congressional battles over Social Security reform. Nevertheless, similarly radical restructurings of reimbursement have been mandated in the recent past (Medicare in 1965, DRGs in 1983, and managed care in the 1990s), and each time our behavior—and the health care of the nation—was transformed overnight. Evidence-based reimbursement could herald the next great revolution.

Disclosures

None.

References


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